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REMARKS

I. Claim Amendments

Claim 1 has been amended by deleting the expression "capable of forming a semipermeable membrane", and by including a Markush group defining a group of water insoluble polymers.

Support for the Markush group is found at page 8, lines 11-13, of the specification where it is recited that the "water insoluble polymer may be selected among semipermeable water insoluble polymers *like*": ethylcellulose, i.e., a cellulose ether; cellulose acetate, i.e., a cellulose ester; polyvinyl acetate, i.e., a polyvinyl ester; and ammonio methacrylate copolymer type A and type B (Eudragit RL, Eudragit RS), i.e., an acrylic polymer; *etc.*

It is respectfully submitted that the disclosure at page 8, lines 11-13, of the specification supports the amendment. The spirit of the disclosure conveys to the public that Applicants did not intend the claimed invention to be limited to the exemplary few of expressly recited polymers. Rather, it is clear that inclusion of words such as "*like*" and "*etc*" reasonably conveys that the original disclosure was intended to cover water insoluble polymers including cellulose ethers *like* ethylcellulose, cellulose esters *like* cellulose acetate, polyvinyl esters *like* polyvinyl acetate, acrylic polymers *like* ammonio methacrylate copolymer type A and type B (Eudragit RL, Eudragit RS), *etc.*

For all of the foregoing reasons, it respectfully submitted that no new matter has been introduced by the claimed invention.

II. Claim rejections – 35 U.S.C. §112

Claim 1, 3-10, 12-18, 20 and 23-31 are rejected under 35 U.S.C. §112, first paragraph, on the alleged ground that specification is not enabling for the recited feature "water-insoluble polymer capable of forming a semipermeable membrane". The rejection is moot in view of amended claim 1. Withdrawal of the §112 rejection is requested.

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III. Claim Rejections – 35 U.S.C. §103(a)

A. US 6,245,351 to Nara et al. (“Nara”) in view of US 5,753,265 to Bergstrand et al. (“Bergstrand”)

Claims 1, 3, 6-8, 12-18, 20 and 25-29 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Nara in view of Bergstrand.

The claimed invention is characterized by a semipermeable membrane comprising a single polymer composition containing a water insoluble polymer and a modifying agent. The semipermeable membrane is able to disrupt. The water insoluble polymer is selected from the group consisting of cellulose ethers, cellulose esters, polyvinyl esters and acrylic polymers.

In contrast to the claimed invention, Nara discloses a coating composition comprised of two or three polymers:

- a water insoluble polymer;
- a swellable polymer; and
- an optional hydrophilic substance (See claims 1 and 9).

Examples of the water insoluble polymer are disclosed at column 4, lines 5-22, e.g., a cellulose ether, an acrylic polymer, etc. Examples of the swellable polymer are disclosed at column 4, lines 32-59, e.g., hydroxypropyl cellulose (“HPC”), crosslinked acrylic polymers, etc. Examples of the hydrophilic substance are disclosed at column 4, line 64 to column 5, line 8, e.g., hydroxypropylmethyl cellulose (“HPMC”). Such a two- or three-polymer system does not suggest the single polymer coating composition of the claimed invention.

Furthermore, all of the working Examples 1-11 are directed to a coating composition containing 2-3 polymers:

- ethyl cellulose as the water insoluble polymeric component;
- Carbomer/HV1SWAK as the water soluble, swellable polymer; and
- optionally hydroxypropylmethyl cellulose as the hydrophilic polymer.

In summary, Nara discloses a coating composition comprising at least two polymers: a water insoluble polymer and a swellable polymer. Thus, it can be said that Nara teaches away from the claimed invention which is characterized by a semipermeable membrane comprising a single polymer composition containing a water insoluble polymer.

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On page 5 of the Office Action, the Examiner states that Nara does not explicitly teach the addition of a modifying agent in the coating composition. For this purpose, the Examiner relies on the disclosure by Bergstrand of an enteric-coated tablet core having an optional separating layer that is applied onto the core material before applying the enteric coating layer(s). The Examiner alleges that it would have been obvious at the time the claimed invention was made to combine Nara and Bergstrand to arrive at the claimed invention. Applicants respectfully disagree.

Bergstrand discloses that the optional separating layer is prepared from pharmaceutically acceptable compounds, such as those disclosed at column 7, lines 57-63, whether used alone or in mixtures. The optional separating layer may include additives such as plasticizers, colorants, pigments, fillers, anti-tacking and antistatic agents (col. 7, lines 63-67).

Applicants submit that the combination of Nara and Bergstrand fails to suggest the claimed invention since the coating composition disclosed by the primary reference to Nara is characterized by a mixture of two or three polymers: a water insoluble polymer; a swellable polymer; and an optional hydrophilic substance. In contrast, the claimed dosage form is distinguishable over the cited combination of references by a semipermeable membrane comprising a single polymer composition containing a water insoluble polymer and wherein the dosage form is not enteric coated.

Applicants respectfully submit that a *prima facie* case of obviousness has not been established. Accordingly, withdrawal of the §103 rejection of claims 1, 3, 6-8, 12-18, 20 and 25-29 based on the combination of Nara and Bergstrand is requested.

B. Nara, Bergstrand and US 5,225,202 to Hodges et al. ("Hodges")

Claims 30 and 31 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Nara in view of Bergstrand and Hodges.

The Examiner relies on the disclosure by Hodges of an enteric-coated tablet core containing the active and a buffering agent within the range of from about 1 to about 20% by weight (col. 3, lines 20-26). The Examiner concludes, therefore, that it would have been obvious to use an alkaline additive in an amount taught by Hodges to obtain a stable acid-labile composition.

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Claims 30 and 31 are directly dependent on claim 1. For all of the reasons given in Section III(A), above, there would have been no motivation at the time the claimed invention was made to combine Nara and Bergstrand to arrive at the claimed invention, for example as defined by claim 1. Hodges does not overcome the failure of the combination of Nara and Bergstrand to establish a *prima facie* case of obviousness. Accordingly, withdrawal of the §103 rejection of claims 30 and 31 is requested.

**C. Nara, Bergstrand and US 4,795,644 to Zentner ("Zentner") or
US 6,013,281 to Lundberg et al. ("Lundberg")**

Claims 9 and 10 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Nara in view of Bergstrand and Zentner or Lundberg.

Zentner is cited by the Examiner for the alleged disclosure of sodium mono- or di-phosphate as a pH modifying agent. Lundberg is cited for the disclosure of arginine as an alkaline reacting compound.

Claims 9 and 10 are directly or indirectly dependent on claim 1. For all of the reasons given in Section III(A), above, there would have been no motivation at the time the claimed invention was made to combine Nara and Bergstrand to arrive at the claimed invention, for example as defined by claim 1. Neither Zentner nor Lundberg overcomes the failure of the combination of Nara and Bergstrand to establish a *prima facie* case of obviousness. Accordingly, withdrawal of the §103 rejection of claims 9 and 10 is requested.

D. Nara, Bergstrand and WO 98/54171 ("Cotton")

Claims 4, 5 and 23-26 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Nara in view of Bergstrand and Cotton.

As stated by the Examiner on page 8 of the Office Action, Cotton is cited for the disclosure of the magnesium salt of S-omeprazole as an active ingredient. Applicants submit that Cotton does not overcome the deficiencies of Nara and Bergstrand to establish a *prima facie* case of obviousness for the reasons given in Section III(A). Withdrawal of the §103 rejection of claims 4, 5 and 23-26 is requested.

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CONCLUSION

Applicants have made a good faith attempt to respond to the Office Action. It is respectfully submitted that claims 1, 3-10, 12-18, 20 and 23-31 are in condition for allowance, which action is earnestly solicited.

Any fees due in connection with this response should be charged to Deposit Account No. 23-1703.

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Respectfully submitted,

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